UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,134	07/11/2003	Gerold Schuler	100725-37 / Kreisler 1108	4429

27384 7590 08/07/2007

NORRIS, MCLAUGHLIN & MARCUS, PA
875 THIRD AVENUE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,134	SCHULER ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11,29,30,35 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11,29,30,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 6/21/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/07 has been entered.

Claims 31-34 have been cancelled.
Claims 9 and 11 have been amended.
Claims 35-36 have been added.
Claims 9, 11, 29-30, and 35-36 are pending and are under examination.

2. The rejection of the claims under 35 U.S.C. 112 first paragraph is withdrawn in view of Applicant's amendment to the claims.

3. In view of Applicant's amendment, the previous rejection of the claims under 35 U.S.C. 102 is withdrawn. However, Applicant's arguments relevant to the new grounds of rejection will be addressed below.

4. The following are new grounds of rejection.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, 29-30, and 35-36 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed,

specifically:

A method comprising "separating human Tr1-like regulatory cells from CD4+CD25+ T cells (Claim 9, and dependant claims 11, 29-30, and 35-36).

Applicant indicates that support for the new limitations of the claims can be found on page 3 and examples 4 and 5 of the specification, as well as in original claim 4.

A review of the specification fails to reveal support for the new limitations.

At page 3 the specification discloses obtaining Tr1-like regulatory T cells by anergizing CD4+CD25- T cells by contact with CD4+CD25+ T cells. However, the specification does not disclose "separating" the Tr1-like regulatory cells "from CD4+CD25+ T cells. Original claim 4 is drawn to "isolated" Tr1-like regulatory T cells obtainable by anergizing CD4+CD25- T cells. However, "isolated" Tr1 like regulatory T cells does not have the same scope as regulatory T cells "separated" from CD4+CD25+ T cells. Moreover, original claim 4 is drawn to a regulatory T cell obtainable by anergizing a CD4+CD25- T cell, and not to a method of producing a regulatory T cell comprising anergizing CD4+CD25- T cells by contact with CD4+CD25+ T cells. Examples 4 and 5 of the specification describe specific examples in which CFSE labeled CD4+CD25- T cells are cultured at a particular ratio with CD4+CD25+ T cells, followed by FACS sorting the CFSE labeled and unlabelled cells. However, this specific example does not provide adequate support for the more generic method now claimed, which encompasses contacting cells at any ratio, followed by separating the cells by any means.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, 29-30, and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Baecher-Allan et al. (of record).

Baecher-Allan et al. teach a method comprising isolating human PBMC, followed by incubating said PBMC with antibodies, and separating the PBMC into CD4+CD25+ and CD4+CD25- populations by FACS sorting (see page 1246 in particular). Therefore, Baecher-Allan et al. have co-cultured the CD4+CD25- T cells with CD4+CD25+ T cells ex vivo during the incubation with antibodies. Said CD4+CD25- T cells would inherently comprise Tr1 like regulatory T cells that produce IL-10 and suppress proliferation, since they have been contacted with CD4+CD25+ T cells, as recited in the instant claims. Furthermore, said CD4+CD25- T cells have also been contacted in vivo with CD4+CD25+ T cells before isolation.

Thus, the reference clearly anticipates the invention.

Applicant argues that Baecher-Allan et al. do not teach separation after anergizing Tr1-like regulatory T cells. However, the CD4+CD25- T cells taught by Baecher-Allan et al. have been contacted with CD4+CD25+ T cells in vivo and ex-vivo, and would therefore inherently comprise Tr1-like regulatory T cells. Furthermore, the FACS sorting performed by Baecher-Allan et al. results in the separation of the T cell populations.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 9, 11, 29-30, and 35-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Jonuleit et 1., July 15, 2002.

Jonuleit et al. teach a method of producing human regulatory T cells comprising co-culturing CD4+ T cells (which inherently comprise CD4+CD25- T cells) with CD4+CD25+ T cells, followed by separating the regulatory CD4+ T cells from the CD4+CD25+ T cells (see page 256 and 258 in particular). Jonuleit et al. teach that the regulatory T cells suppress proliferation of CD4 T cells (see page 258 in particular). Furthermore, the regulatory T cells taught by Jonuleit et al. would inherently produce IL-10, since they have been obtained by a method identical to that of the instant claims. Additionally,

the regulatory T cells taught by Jonuleit et al. have also been contacted with CD4+CD25+ T cells in vivo before isolation.

Thus, the reference clearly anticipates the invention.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600

7/6/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER